IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC. Defendants.	C.A. No. 22-252 (JDW)
MODERNA, INC. and MODERNATX, INC., Counterclaim Plaintiffs, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Counterclaim Defendants.	[redacted] REDACTED - PUBLIC VERSION

MODERNA'S *DAUBERT* MOTION

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TABLE OF ABBREVIATIONS

Abbreviation	Full Description
§ 1498	28 U.S.C. §1498(a)
'435 Patent	U.S. Patent No. 9,364,435
'651 Patent	U.S. Patent No. 9,504,651
Arbutus	Arbutus Biopharma Corp.
Chula	Chulalongkorn University
FAR	Federal Acquisition Regulation
Genevant	Genevant Sciences GmbH
LNP	Lipid nanoparticle
Moderna	Moderna, Inc. and ModernaTX, Inc. collectively
mol%	Molar amount of a substance is the amount of that substance measured in moles. A mole is a unit of measurement to express amounts of a chemical substance. Molar percentage of a lipid in a mixture refers to the proportion of moles of a specific lipid relative to the total moles of all lipids.
Patents-in-Suit	U.S. Patent Nos. 9,504,651; 9,364,435; 8,492,359; and 11,141,378
Plaintiffs	Arbutus and Genevant collectively
Ratio Patents	U.S. Patent Nos. 9,364,435; 8,492,359; and 11,141,378
SEC	U.S. Securities and Exchange Commission
UC	Ultracentrifugation

TABLE OF EXHIBITS

Exhibit #	Exhibit Description
A	Expert Report of Catharine M. Lawton with Excerpted Schedules (dated November 25, 2024)
B	Rebuttal Expert Report of Catharine M. Lawton (dated February 14, 2025)
C	Reply Expert Report of Catharine M. Lawton (dated March 21, 2025)
D	Deposition Transcript Catharine M. Lawton (April 30, 2025)
E	Opening Expert Report of Dr. Michael Mitchell (dated November 25, 2024)
F	Reply Expert Report of Dr. Michael Mitchell (dated March 21, 2025)
G	Opening Expert Report of Dr. Georg Schuster of Coriolis Pharma (dated November 24, 2024)
H	Deposition Transcript Dr. Georg Schuster (April 11, 2025)
I	Excerpts of Rebuttal Expert Report of Owen Shea Fenton, Ph.D. (dated February 11, 2025)
J	Excerpts of Rebuttal Expert Report of Robert Prud'homme, Ph.D. (dated February 14, 2025)
K	Third Sur-Reply Expert Report of Robert Prud'homme, Ph.D. (dated August 4, 2025)
L	Deposition Transcript of Dr. Georg Schuster (August 6, 2025)
M	Rebuttal Expert Report of Peter J. Pitts (dated February 14, 2025)
N	Responsive Expert Report of Alex M. Brill (dated February 14, 2024 [*sic*])
O	Deposition Transcript Excerpts of J. Schariter (May 8, 2024)
P	Deposition Transcript Excerpts of D. Parsons (June 7, 2024)
Q	G. Schuster Presentation to Plaintiffs' Counsel (dated September 18, 2024) (GENV-01102754)
R	Genevant Sciences GMBH License (GENV-00023616)
S	Genevant Sciences GMBH License (GENV-00022307)
T	Deposition Transcript of Dr. Michael Mitchell (dated April 30, 2025)
U	Reply Expert Report of Dr. Georg Schuster (dated March 19, 2025)
V	First Supplemental Expert Report of Catharine M. Lawton with Amended Schedule 6.1 (dated January 28, 2025)

I. INTRODUCTION

Plaintiffs' endgame is clear: desensitize the jury to Plaintiffs' multi-billion-dollar damages ask and encourage the jury to punish Moderna. Plaintiffs do this by leveraging their experts as mouthpieces to spin an inaccurate narrative of Moderna's "intent," cherry-pick datapoints that overestimate Moderna's potential profit while ignoring actual financials, prop up bespoke litigation-driven infringement testing, and interject policy arguments that maximize Moderna's liability. However, these opinions fail the requirements of Rule 702 and *Daubert* because they are unreliable, not the product of sound principles and methodology, not tied to the facts of this case, and not the proper subject of expert testimony. The Court should exercise its role as gatekeeper to exclude such unreliable and prejudicial testimony.

II. NATURE AND STAGE OF PROCEEDINGS

Plaintiffs filed their complaint on February 28, 2022, alleging that Moderna infringed six patents. Following completion of fact and expert discovery, the Court ordered case narrowing. At present, 15 claims are asserted across four patents. Summary judgment briefing was completed on September 23, 2025. D.I. 545. Trial is scheduled to begin on March 9, 2026. D.I. 485.

III. SUMMARY OF ARGUMENT

The Court should exclude Ms. Lawton's $4+ billion reasonable royalty damages opinion under her purported "analytical method." That method is applicable when comparison is available between a defendant's usual profits absent infringement (*e.g.*, profits that do not include sales of the accused products) and a defendant's profits for accused product. When done correctly, the analytical method uses the difference between the accused infringer's "usual or acceptable" profits and "anticipated" profits of the accused product to isolate the value of the patented technology. But that method does not fit the facts of this case, as Ms. Lawton admitted. She conceded that it is "self-evident" that there is no "usual" profit to point to for the accused vaccine—Moderna's first

commercial product. To make matters worse, Ms. Lawton does not even correctly apply the analytical method. Because there is no objective "usual or acceptable" profit, she creates her own "analytical method" by manufacturing two ***different*** per-dose "profits" for the ***same*** accused product (one she terms "anticipated" and the other she synonymously calls "expected"), then subtracts one from the other. This is not the analytical method, or any other reliable method for calculating damages.

The Court should also exclude Ms. Lawton's separate $5+ billion reasonable royalty damages opinion under her hypothetical negotiation approach, which is based entirely on non-comparable agreements and an arbitrarily selected profit split. Every agreement Ms. Lawton relies on includes far more rights than just the Patents-in-Suit (if they include them at all), yet she makes no effort to apportion and plucks a 25%/75% profit split from the unreliable range she orchestrates.

The Court should additionally exclude Ms. Lawton's deluge of statements concerning Moderna's ***intent***, *e.g.*, that Moderna "knowingly and deliberately tried to hide its infringement" and that Moderna manipulated its stock price and hoodwinked the SEC. Ms. Lawton has no knowledge about Moderna's subjective intent, nor can an expert offer an opinion about a party's subjective state of mind. *Wirtgen Am., Inc. v. Caterpillar, Inc.*, 2024 WL 166833, at *2 (D. Del. Jan. 16, 2024); *Shire Viropharma Inc. v. CSL Behring LLC*, 2021 WL 1227097, at *5 (D. Del. Mar. 31, 2021) (experts may ***not*** provide testimony concerning state of mind or culpability). This testimony only serves to inflame the jury so that they award Plaintiffs' outsized damages demand.

The Court should also exclude Dr. Schuster's infringement-testing opinions because they are not the product of reliable methodology. Dr. Schuster served a report describing testing his lab performed to prove that Moderna's vaccine used lipid amounts that fall within the claimed ranges of the Ratio Patents. But once Plaintiffs produced the ***full*** set of Dr. Schuster's testing materials

(by Court order, after Moderna moved to compel), the fundamental flaws in his testing became clear. Dr. Schuster's made-for-litigation methodology creates significantly different results for the ***same*** sample, *i.e.*, in one test run, lipid component would fall within the claimed range, and in another run, that same sample's lipid component would be outside the claimed range. Worse still, Dr. Schuster ran undisclosed pretesting to adjust the parameters to maximize infringing results. This unreliable, "[r]esult-driven analysis" should be excluded. *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig. (No II)*, 892 F.3d 624, 634 (4th Cir. 2018).

The Court should likewise exclude Dr. Mitchell's non-expert, attorney-disguised statements and opinions regarding Moderna's state of mind and culpability, which stray far beyond the realm of permissible expert testimony. For instance, Dr. Mitchell improperly claims, *e.g.*, that "Moderna willfully infringed" because it "was ***aware*** that the Accused Product infringed," "***believed***" certain formulation changes were needed, and "attempted to ***conceal*** its infringement" with a "***desire*** to hide." *See Wirtgen*, 2024 WL 166833, at *2; *Shire*, 2021 WL 1227097, at *5.

Finally, the Court should exclude the opinions of Mr. Pitts and Mr. Brill regarding 28 U.S.C. § 1498(a). Their opinions are simply statutory interpretation (a role for the Court, not experts) and policy arguments (which are improper subjects of expert testimony). Any additional material they offer is amicus-like commentary on whether the Government's procurement of millions of vaccine doses benefitted the Government or the public. That is not the product of ***any*** accepted principles and methods, much less ***reliably applied*** principles and methods.

IV. STATEMENT OF FACTS

Plaintiffs accuse Moderna's COVID-19 vaccine of infringing four patents from two patent families: the '651 Patent claims lipid formulations with certain percentages of "fully encapsulated" mRNA; the Ratio Patents claim nucleic acid-lipid particles with various lipid ratios (Ratio Patents). The accused vaccine is Moderna's first commercial product. Moderna launched it in 2020, in

partnership with the Government, which ordered 500 million doses through a procurement contract as part of Operation Warp Speed, a multi-agency government effort to accelerate the development, production, and distribution of a COVID-19 vaccine. Among other experts, Plaintiffs present testing from Dr. Schuster to purportedly show that Moderna's vaccine contains some LNPs with lipids within the Ratio Patents' claims, infringement opinions from Dr. Mitchell based on Dr. Schuster's testing, and damages opinions from Ms. Lawton on reasonable royalty and secondary considerations of non-obviousness. Both Dr. Mitchell and Ms. Lawton further opine on Moderna's intent. Plaintiffs also offer opinions by Mr. Pitts and Mr. Brill that vaccine doses Moderna made for and sold to the Government provided no "benefit" to the Government under § 1498.

V. LEGAL STANDARD

Rule 702 requires trial court judges to assume "a gatekeeping role" to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharma., Inc.*, 509 U.S. 579, 589 (1993). As the Advisory Committee explained, "[j]udicial gatekeeping" ensures an expert's conclusions do not "go beyond what the expert's basis and methodology may reliably support." Committee Notes (2023). The trial court's gatekeeping function requires more than simply "taking the expert's word for it." Committee Notes (2000). The party offering the expert testimony has the burden of establishing its admissibility. *Id.*

VI. MS. LAWTON'S UNRELIABLE OPINIONS, INCLUDING DAMAGES, SHOULD BE EXCLUDED

Plaintiffs' damages expert Ms. Lawton offers two alternative royalty theories for the damages Moderna owes for its COVID-19 vaccine sales through January 2024—one over $4 billion, the other over $5 billion. Ex-A ¶¶1205-11, 1644-62, Scheds. 1.1-1.2. Both of her damages opinions are wholly unreliable and, together with her inflammatory and prejudicial comments on Moderna's intent, should be excluded.

A. Ms. Lawton's Analytical Method Should Be Excluded

Ms. Lawton's "analytical method" reaches over $4 billion in damages. Ex-A ¶¶1212-90, 1647-48. *TWM Mfg. Co. v. Dura Corp.* sets out the framework for the analytical method, and explains that a reasonable royalty can be calculated by "subtract[ing] the infringer's ***usual or acceptable net profit*** from its ***anticipated net profit*** realized from sales of infringing [products]." 789 F.2d 895, 899 (Fed. Cir. 1986); Ex-D 36:17-40:11; Ex-A ¶¶1212-18. A fundamental premise of the analytical method is that profits that do not reflect the value of the patented technology (*i.e.*, those that are "usual or acceptable") are subtracted from "anticipated" profits of the accused product. The difference can then be ascribed to "the benefit accorded by the patents at issue." *Energy Transp. Grp., Inc. v. William Demant Holding A/S*, 697 F.3d 1342, 1357 (Fed. Cir. 2012); *Metaswitch Networks Ltd. v. Genband US LLC*, 2016 WL 874737, at *5 (E.D. Tex. Mar. 5, 2016).

But that is not what Ms. Lawton does. Instead, Ms. Lawton creates two different per-dose "profits" for the ***same*** and ***only*** accused product, neither of which is based on Moderna's actual sales data, and subtracts them. Ex-A ¶¶1219-90, Scheds. 3.1-3.3. Ms. Lawton does this because one of the required inputs for the analytical method—Moderna's "usual or acceptable" net profit—***does not exist*** in this case because Moderna's ***first*** commercial product ***is*** the accused product (as Ms. Lawton readily admits). Ex-A ¶56; Ex-D 45:24-46:13, 267:2-12. And although an industry standard profit can be used lieu of the accused infringer's "usual or acceptable" profit, *Sprint Commc'ns Co. LP v. Charter Commc'ns, Inc.*, 2021 WL 982732, at *11 (D. Del. Mar. 16, 2021), Ms. Lawton explicitly did ***not*** do so. Ex-D 40:12-15, 41:10-42:6. Courts have not hesitated to strike damages experts who fail to properly apply the analytical method, such as by failing to account for differences in technology, *Abbott Diabetes Care Inc. v. DexCom Inc.*, 2024 WL 6887335, at *2 (D. Del. Jan. 17, 2024) (excluding Ms. Lawton's "analytical approach"), or by basing calculations on unsupported estimates of the patented feature's value, *NetAirus Techs., LLC*

v. Apple, Inc., 2013 WL 11237200, at *4 (C.D. Cal. Oct. 23, 2013).

Ms. Lawton's "analytical method" is fatally flawed. ***First***, it is inapplicable to the facts of this case. Correctly employing the analytical method depends on knowing the accused infringer's "usual or acceptable" net profit. *TWM*, 789 F.2d at 899. Ms. Lawton, however, admitted that "a usual or acceptable net profit" did not "have a meaning" for Moderna because, as a startup, pre-commercial company, Moderna had ***no*** commercial track record. Ex-D 45:24-46:13; 267:6-12. Without this factual premise of an accused infringer's "usual or acceptable" net profit, which is one of two required inputs for the analytical method, this methodology cannot satisfy Rule 702's "fit" requirement. Fed. R. Evid. 702(d) ("expert's opinion reflects a reliable application of the principles and methods ***to the facts of the case***"); *Daubert*, 509 U.S. at 591.

Second, Ms. Lawton is not reliably applying the analytical method here. Because there was ***no*** "usual or acceptable" net profit, Ms. Lawton fashioned her own "usual or acceptable net profit" based on a mishmash of cherry-picked datapoints of "expected" and "estimated" profits for Moderna's COVID-19 vaccine, and subtracted that from what she calculated as Moderna's "anticipated" profits for the same COVID-19 vaccine. Ex-A ¶¶1230-59, Scheds. 3.1-3.2; Ex-D 48:15-52:7. That is, she took the difference of what she calculated as Moderna's "anticipated" profit to what she made up as Moderna's "usual and acceptable" profit—both based ***solely*** on the same ***identical accused product***. That is neither the analytical method nor a reliable application of the analytical method. *See 10x Genomics, Inc. v. NanoString Techs., Inc.*, 690 F. Supp. 3d 449, 464 (D. Del. 2023) ("differences between the products may be attributable to the fact that the [accused] GeoMx product is enabled by the patents-in-suit, as compared to nCounter, which does not"); *Wonderland Switzerland AG v. Evenflo Co., Inc.*, 564 F. Supp. 3d 320, 341 (D. Del. 2021); *Abbott*, 2024 WL 6887335, at *2. Indeed, creating a net profit for the accused product to use as

the "usual or acceptable" profit defeats the purpose of the analytical method, which seeks to isolate the value of the patented technology by ***subtracting*** from an accused infringer's anticipated profits the accused infringer's usual margins, *i.e.*, what the accused infringer usually obtains without using the patented technology. Ms. Lawton's methodology does not even purport to achieve that result and therefore is not a reliable application of the analytical method.

In addition, Ms. Lawton's so-called "analytical method" is so convoluted that even she could not keep the inputs to her calculation straight. Her report, calculations, and schedules identify multiple "anticipated [net]" profits. *See* Ex-A ¶¶1219-59, Chart 6.1, Scheds. 3.1-3.3. But when asked in her deposition to identify her calculated "usual" profits and "anticipated" profits, she identified the ***same*** input, $6.10, as ***both*** Moderna's usual or acceptable net profit ***and*** Moderna's anticipated net profit—a calculation that would result in ***zero dollars*** in damages. Ex-D 132:21-133:4, 134:2-135:2, 260:25-268:1; *see also id.* 95:16-96:1 (testifying "that's the math, but the math is not applicable"), 125:3-23. These flaws in Ms. Lawton's analytical method are not curable by cross-examination; they fall within the heartland of Rule 702 and this Court's gatekeeping function. *EcoFactor, Inc. v. Google LLC*, 137 F.4th 1333, 1345-46 (Fed. Cir. 2025) (en banc) (damages opinion "was not based on sufficient facts or data," which "renders [expert's] testimony unreliable and therefore inadmissible"); *Orthoflex, Inc. v. ThermoTek, Inc.*, 986 F. Supp. 2d 776, 798-99 (N.D. Tex 2013) ("opportunity for cross-examination is not of itself sufficient to cure expert testimony that is unreliable under *Daubert*"); *Abbott*, 2024 WL 6887335, at *2.

B. Ms. Lawton's Hypothetical Negotiation Approach Should Be Excluded

Ms. Lawton's alternative "hypothetical negotiation approach" theory calculates over $5 billion in damages. Ex-A ¶¶1534, 1645-46; *see generally id.* ¶¶1291-1538. She largely eschews Plaintiffs' own licenses for the Patents-in-Suit, structured as a percent running royalty based on net sales, deeming them "at best, *only minimally* economically comparable." *Id.* Table 6.7, ¶¶995,

981, 1002, 1009, 1019, 1030; *see generally id.* ¶¶919-1038, Sched. 6.1; Ex-V ¶¶9-14. Instead, Ms. Lawton calculates a range of "profit splits" based on four unreliable and unapportioned datapoints. Ex-A ¶¶1371-93. She does nothing, however, to account for the fact that these datapoints include far more extensive rights (*e.g.*, license to an entire portfolio of patents in addition to the Patents-in-Suit, Plaintiffs' "know-how," manufacturing support) than what Moderna would receive in the hypothetical negotiation. *See* Ex-R at 621 ("Genevant Know-How"), 631 ("R&D Support Plan"); Ex-S at 313 ("Genevant Outside Foreground IP"), 315 ("Manufacturing Know-How"), 324 ("Development"), 352-402 (licensed portfolio); Ex-D 184:7-191:13, 195:10-198:8. Ms. Lawton then plucks a profit split of 25% Plaintiffs/75% Moderna and applies that profit split to ***projected*** (not actual) profits, resulting in a per-dose royalty of $4.77 for what she deems the "pandemic phase" and $6.61-$10.56 for her supposed "endemic phase." Ex-A ¶¶1393, 1532-38, 1349-53.

But where, as here, the hypothetical negotiation approach purports to rely on comparable licenses, Federal Circuit law "require[s] a party to account for differences in the technologies and economic circumstances of the contracting parties." *Apple Inc. v. Wi-LAN Inc.*, 25 F.4th 960, 971 (Fed. Cir. 2022). An expert must do more than simply list out differences. "[U]nsubstantiated conclusions about economic comparability, lacking in analysis . . . provide nothing more than *ipse dixit*" and should be excluded. *M2M Sols. LLC v. Enfora, Inc.*, 167 F. Supp. 3d 665, 678 (D. Del. 2016). Moreover, "expert testimony should be excluded when it fails to allocate license fees among the licensed patents." *Rex Med., L.P. v. Intuitive Surgical, Inc.*, 1025 WL 2799030, at *4 (Fed. Cir. Oct. 2, 2025). "A failure to apportion goes to admissibility, not weight." *Wirtgen Am., Inc. v. Caterpillar, Inc.*, 715 F. Supp. 3d 587, 593 (D. Del. 2024). Ms. Lawton's hypothetical negotiation approach violates these requirements and creates an unreliable "range" of profit splits before she arbitrarily picks 25%/75%. Ex-A ¶¶1371-93, Table 6.7; *LaserDynamics, Inc. v. Quanta Comput.,*

Inc., 694 F.3d 51, 69 (Fed. Cir. 2012) (arbitrary one-third apportionment to expert's royalty rate "appears to have been plucked out of thin air"); *Parallel Networks Licensing, LLC v. Int'l Bus. Machs. Corp.*, 2017 WL 1405155, at *3-5 (D. Del. Apr. 17, 2017) (excluding damages theory because expert applied multiple flawed assumptions, each one of which was sufficient to call damages conclusion into question). Her hypothetical-negotiation approach should be excluded.

1. Ms. Lawton's "Comparable" License Analysis Is Unreliable

Ms. Lawton's profit split range from her alleged "comparable" license analysis is based on four unreliable and unapportioned datapoints. ***First***, Ms. Lawton points to a December 2019 life science survey that looked at 35 agreements from 2015 to 2019 and describes "typical profit splits" from ***co-commercialization*** schemes (rather than the naked license at issue here). Ex-A ¶1384. Ms. Lawton has ***no*** technical comparability analysis for the survey and admitted that ***none*** of the agreements surveyed relate to a COVID-19 vaccine or the Patents-in-Suit. Ex-D 211:10-16, 214:4-14, 214:20-25; Ex-A Table 6.8. Ms. Lawton further makes no effort to apportion those agreements' profit splits for the value of any licensed patents. Ex-A ¶¶1387-93. That is improper. *M2M Sols. LLC v. Motorola Sols., Inc.*, 2016 WL 767900, at *6 (D. Del. Feb. 25, 2016) (excluding opinion that relied on "survey unrelated to the patented invention"); *Lighting Def. Grp. LLC v. Shanghai Sansi Elec. Eng'g Co.*, 2024 WL 4837011, at *8 (D. Ariz. Nov. 20, 2024) (excluding expert that sought to opine on "industry practice" as "comparable" without explaining how the practice related to the specific technology or parties in suit).

Second, Ms. Lawton relies on three Moderna collaboration and co-commercialization agreements [redacted], a 2017 Moderna document discussing contemplated "deal structures," and testimony from a Moderna witness that [redacted] which was expressly qualified by the recognition that "[e]very deal is different" such that only "[c]ertain

deals [redacted]." Ex-A ¶¶1380-86, 1042-75, 406-07. Ms. Lawton concedes none are related to COVID-19, none involve a license to any of the Patents-in-Suit, and none are apportioned for the value of the Patents-in-Suit. Ex-A ¶¶1051-56, 1063-65, 1071-73, 1379-83, 1385-86; Ex-D 215:4-216:4, 218:10-21, 219:12-220:22. Ms. Lawton also agrees that the Moderna collaboration agreements include far more than "a naked patent license." Ex-A ¶1380. But pointing out these differences is insufficient, and "[w]hat's utterly lacking is evidence that [Ms. Lawton] met [her] obligation to 'account for such distinguishing facts' in invoking the [agreements] to value the" Patents-in-Suit. *Omega Pats., LLC v. CalAmp Corp.*, 13 F.4th 1361, 1381 (Fed. Cir. 2021); *Roland Corp. v. inMusic Brands, Inc.*, 2025 WL 926703, at *13 (Fed. Cir. Mar. 27, 2025) (vacating entire jury award because damages expert "'merely *identified*' a difference in the patents covered by [allegedly comparable] licenses" without more (emphasis in original)); *Enfora*, 167 F. Supp. 3d at 677-79; *Motorola*, 2016 WL 767900, at *8.

Third, Ms. Lawton nominally relies on six of Plaintiffs' license agreements, all of which she describes as "at best, ***minimally*** economically comparable given the cardinal differences between those agreements and the hypothetical negotiation." Ex-A ¶¶1376-78, Table 6.7. She further acknowledges that each of these agreements licensed are not "naked licenses to the Patents-in-Suit" and include other patents and rights that would ***not*** be part of a license from the hypothetical negotiation. *Id.* ¶1377. Once again, Ms. Lawton does no more than pay lip service to these differences, *Omega*, 13 F.4th at 1381, and she fails to establish that the Patents-in-Suit drove any of these licenses. *See Apple*, 25 F.4th at 973; *Fundamental Innov. Sys. Int'l LLC v. Anker Innovs. Ltd.*, 2025 WL 459916, at *12-13 (D. Del. Feb. 11, 2025) (excluding damages opinion where expert failed to establish asserted patents drove licenses or adjust for differences with scope of hypothetical negotiation). The failure to account for only the value of the patented technology

is why Ms. Lawton's opinion warrants exclusion here. *See Abbott*, 2024 WL 6887335, at *2.

In addition, five of the licenses have running royalty rates (not profit splits) of [redacted]—well below Ms. Lawton's "range" of [redacted] to [redacted] Ex-A ¶1374, Table 6.7. The only agreement that has a profit split, [redacted] does ***not*** include the Patents-in-Suit and is limited to [redacted]. Ex-D 195:10-23, 196:18-198:8. Even for [redacted] Ms. Lawton would not agree that the license fees, including the profit split, were apportioned for the Patents-in-Suit. Ex-D 188:20-191:13, 195:10-23 (Q: "[D]o you have any understanding one way or the other as to whether the profit split includes the value of the licensed patents or any other technology that was licensed or provided to [redacted] under this agreement?" A: "Again, the terms are the terms."), 185:9-186:10. There is nothing reliable or helpful to the jury about Ms. Lawton's analysis. Where the patentee has failed to account for the value of unpatented features, the Federal Circuit has held that the patentee has failed to prove damages. *See NNCrystal US Corp. v. Nanosys, Inc.*, 2023 WL 2891453, at *3 (D. Del. Apr. 11, 2023) (excluding unapportioned damages opinion that merely "recogniz[ed] that the licenses [] analyzed included additional patent and technology rights," without "explain[ing] how those licenses are sufficiently comparable such that further apportionment is not necessary"); *Sprint Commc'ns. Co. v. Comcast IP Holdings, LLC*, 2015 WL 456154, at *2 (D. Del. Jan. 30, 2015) (precluding testimony where "all of the agreements license a number of patents, all of which are not in suit"); *SmartSky Networks, LLC v. Gogo Bus. Aviation LLC*, 2025 WL 2972258, at *8-9 (D. Del. Oct. 21, 2025).

Fourth, the May 29, 2013, ***unaccepted*** Tekmira ***offer***, which included a running royalty of 7% and occurred before issuance of any of the Patents-in-Suit, does not support Ms. Lawton's range of profit splits or her 25%/75% conclusion. Ex-A ¶1373, Table 6.7. An unaccepted offer "has limited, if any, value for determining reasonable royalty," particularly, where, as here, the

offer was made seven years before the hypothetical negotiation and before COVID-19 even existed. *MiiCs & Partners, Inc. v. Funai Elec. Co.*, 2017 WL 6268072, at *4 (D. Del. Dec. 7, 2017); *In re ChanBond, LLC Pat. Litig.*, 2020 WL 550786, at *1 (D. Del. Feb. 4, 2020) (excluding "investment solicitations" that "took place some ten to twelve years before the date of the hypothetical negotiation"); *TC Tech. LLC v. Sprint Corp.*, 2019 WL 2515779, at *9 (D. Del. June 18, 2019) (excluding opinion that failed to explain why an "opening offer in a negotiation" was "a reliable measure of a rate resulting from the hypothetical negotiation"). Ms. Lawton's insistence on the relevance of the Tekmira offer cannot be squared with her dismissal of other datapoints that also pre-date COVID. Ex-A ¶¶923, 928. Like all the other licenses she considered "comparable," the Tekmira offer included more than a bare patent license, which Ms. Lawton fails to account for and which warrants exclusion. Ex-A ¶¶339-40, 1354-55, Fig. 6.26; *Rex*, 2025 WL 2799030 at *7-8; *Abbott*, 2024 WL 6887335, at *2.

Ms. Lawton also uses the unaccepted 2013 Tekmira offer as an anchor to shoehorn in "technology licensing discussions" and correspondence between Plaintiffs and Moderna from 2018 up to as recently as 2021. Ex-A ¶¶217-30, 373-81, 522, 811-15, 905-18, 1125-27, 1169-72, 1413-15. However, these communications were subject to Rule 408 and therefore inadmissible. *See* Fed. R. Evid. 408(a); *PharmaStem Therapeutics, Inc. v. Viacell Inc.*, 2003 WL 22387038, at *3-4 (D. Del. Oct. 7, 2003) (excluding all evidence relating to negotiations ***and*** license agreements that arose in context of threatened litigation).

Ms. Lawton's profit split analysis is based on non-comparable agreements that she failed to apportion. Her opinion should be excluded. *SmartSky*, 2025 WL 2972258, at *8-10 (excluding reasonable royalty opinion for using a contract that is not sufficiently comparable and failing to apportion value of allegedly infringing features from value of all other features); *Omega*, 13 F.4th

at 1381; *Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Grp., LLC*, 879 F.3d 1332, 1351 ("Regardless of how low the royalty rate, the expert must still apportion damages and sufficiently tie the royalty rate ***to the facts of the case***"); *Fundamental Innov.*, 2025 WL 459916, at *13-14; *Baltimore Aircoil Co., Inc. v. SPX Cooling Techs. Inc.*, 2016 WL 4426681, at *24-25 (D. Md. Aug. 22, 2016), *aff'd*, 721 F. App'x 983 (Fed. Cir. 2018) (no amount of cross-exam can cure defect of expert's failure to offer any details a license was comparable to specific facts of case).

2. Ms. Lawton's 25%/75% "Profit Split" Is Arbitrary

Based on her flawed analysis of agreements discussed above, Ms. Lawton lands on what she claims is a profit split of 25% Plaintiffs/75% Moderna. In reality, Ms. Lawton's profit split is 50%/50%, but she obscures that by converting her percentage split into a per-unit royalty. Regardless, Ms. Lawton does not justify ***why*** or ***how*** she selected this profit split. Instead, she identifies a negotiation range of [redacted] claims 20%/80% is supported by her industry report and a Moderna 2017 slide deck, claims that Plaintiffs were in the "driver's seat," and lands on 25%/75%. Ex. A ¶¶ 1374, 1381, 1384-86, 1443-44, 1537. This arbitrary selection of 25%/75% is the same type of expert opinion that the Federal Circuit held was unreliable in *Exmark* and the same error that the Court identified in excluding Ms. Lawton's opinions in *Abbott*, 2024 WL 6887335 at *2. In *Exmark*, the expert "concluded with little explanation" that the parties would have agreed to a 5% reasonable royalty rate for the value of an improved baffle in lawn mowers. 879 F.3d at 1349. The Federal Circuit held that opinion inadmissible, noting that while the expert "identified a number of advantages arising from the use of the claimed baffle," she did not explain how these advantages, or her "superficial recitation of the *Georgia-Pacific* factors," led to her proposed 5% royalty rate. *Id.* at 1349-51 ("we cannot agree that using an allegedly low royalty rate alone supports the admissibility of the expert's reasonable royalty opinion," especially where the expert "plucked the 5% royalty rate out of nowhere"); *see also Uniloc USA, Inc. v. Microsoft*

Corp., 632 F.3d 1292, 1315 (Fed. Cir. 2011) (rejecting 25% "rule of thumb" as a "fundamentally flawed tool for determining a baseline royalty rate . . . because it fails to tie a reasonable royalty base to the facts of the case at issue"). Further underscoring the arbitrariness of Ms. Lawton's profit split, her per-unit royalty rate varies by magnitudes ($4.77 to $6.61-$10.56) depending on when the vaccine dose was sold—even though she admitted that the footprint of the invention was identical regardless of when the vaccine was sold. Ex-A ¶1538; Ex-D 33:6-36:10.

Ms. Lawton's profit split is arbitrary for the additional reason that the starting point of her analysis, Moderna's so-called expectations, is unreliable. While the parties' expectations are relevant to the hypothetical negotiation, that does not obviate the requirement that an expert present reliable evidence of those expectations. Ms. Lawton has none. For the pandemic phase, she creates her own outsized per-dose profit of $19.07 based on a document that assumes a $24.03/dose price and scaling the numbers "up" to a price of $30/dose (neither price being what Moderna charged during the pandemic). Ex-A ¶¶484, 1230-43, 1281, 1288, 1332, Table 6.3, Fig. 6.16; Ex-D 122:7-17. While Ms. Lawton claims that this is the profit Moderna "expected," she does no analysis to support that conclusion and simply asserts that Moderna's initial analysis of possible pricing counts as an expectation. *EcoFactor*, 137 F.4th at 1341 (fundamental premise of damages opinion was "untethered" and "unsupported by the evidence" on which expert relied). Ms. Lawton's endemic phase per-dose profit of $26.43-$42.23 solely relies on aggressive "Upside" forecasts of per-dose prices (ranging from $44-$60) that were similarly never realized. Ex-A ¶¶1350-53, Tables 6.5, 6.25. By assessing only Moderna's potentially most optimistic pricing and profit projections, as opposed to Moderna's actuals, which reflect ***negative*** profit margins in the endemic phase, Ms. Lawton's endemic phase calculations are even further removed from the evidence of Moderna's actual sales, actual costs, and actual profits. Ex-A, Sched. 7.3 (reflecting ***net operating***

losses for Sept. 2023 to Jan. 2024), Table 6.6 (showing from Dec. 2020 to Jan. 2024, Moderna had only a $8.72/dose operating profit ($9,710,555,778 ÷ 1,113,852,185 doses = $8.72/dose)).

Ms. Lawton attempts to defend her analysis by claiming she focused on expectations at the time of the hypothetical negotiation. But the hypothetical negotiation takes into account the book of wisdom, which includes events after the hypothetical negotiation. *St. Clair Intell. Prop. Consultants, Inc. v. Canon, Inc.*, 2004 WL 2213562, at *2 (D. Del. Sept. 28, 2004) ("[C]ourts may consider events after the date infringement began as a basis for inferring what the pre-infringement negotiated value of a license would have been."). Ms. Lawton herself considers events that occur ***after*** the May 2020 hypothetical negotiation when convenient for her opinions. For example, Ms. Lawton relies on the Oct. 2020 [redacted] agreement as alleged "explicit evidence of Genevant's profit split" and the aggressive "Upside" Sept. 2020 Moderna forecasts to support her inflated endemic phase profitability estimates. Ex-A ¶¶1400-02; *see also Bitmanagement Software GmbH v. United States*, 2022 WL 17077251, at *9-10 (Fed. Cl. Nov. 1, 2022) (allowing consideration of post-hypothetical-negotiation information and noting that "Plaintiff's argument [seeking exclusion of Defendants' use] is inconsistent because [Plaintiff] too relies on facts *after* the . . . negotiation date for its damages' calculation" (emphasis in original)). At bottom, Ms. Lawton's arbitrary and unreliable starting point inflates the damages demand well beyond the footprint of the invention and skews the damages horizon for the jury. *Uniloc*, 632 F.3d at 1320 ("[T]he $19 billion cat was never put back into the bag," even after cross-examination and jury instruction.).

C. Ms. Lawton's Intent-Based Opinions Should Be Excluded

Ms. Lawton's damages and secondary considerations reports include ***significant*** commentary on Moderna's intent. "It is well settled that experts may not provide testimony concerning 'the state of mind' or 'culpability' of defendants, corporations, regulatory agencies, and others." *Shire*, 2021 WL 1227097, at *5; *Zimmer Surgical Inc. v. Stryker Corp.*, 365 F. Supp.

3d 466, 497 (D. Del. 2019). Yet that is precisely what Ms. Lawton does, opining on what Moderna "knowingly" or "deliberately" did, "expected," "believed," or "concluded." Ex-A ¶¶1665-90 (Moderna "deliberately tried to hide evidence of its use," and "took efforts to remove references to language that could be perceived as crediting the contributions and inventions of others"), ¶147, ¶180 ("Moderna's decision to transition from MC3 to SM-102 was ***motivated by*** … ***avoiding having to pay royalties for commercial products to Plaintiffs***."); VII.C. header ("Moderna ***knowingly and deliberately tried to hide*** its infringement"), Ex-C ¶537. Ms. Lawton also opines that Moderna's "paranoid" CEO Stéphane Bancel made false statements that Moderna was not using Plaintiffs' claimed LNP technology, Ex-A ¶¶120, 366-67; Ex-C ¶¶334, 385, and asserts, without merit, that Moderna's executives manipulated its stock price. Ex-A ¶¶117-20, 266-302; Ex-C ¶512 ("facts clearly establish that Moderna did not conform to industry practices and in view of Moderna's long history of 'misrepresentations'"). None of this has anything to do with a proper and reliable calculation of monetary damages. Ms. Lawton's opinions on Moderna's intent are inflammatory, improper, and should be excluded. *Shire*, 2021 WL 1227097, at *5 ("question of intent constitutes a classic jury question"); *Wirtgen*, 2024 WL 166833, at *2 (excluding willfulness opinions because expert had "no knowledge about [defendant's] subjective state of mind").

While Ms. Lawton claimed that she has no opinions on willfulness, Ex-D 10:4-12, that assertion clearly is contravened by the "Willful Infringement" section setting out facts relevant only to willfulness, like Moderna's alleged copying of the patents. *E.g.*, Ex-A ¶1161 ("Moderna engaged in substantial copying of Plaintiffs' innovations"); ¶1675; Ex-B ¶137; Ex-C ¶¶359, 506 ("Moderna's IP strategy from the beginning was to attempt to avoid paying patent royalties"). Ms. Lawton has no specialized knowledge to opine on any alleged infringement or copying, Ex-A ¶1 (identifying herself as a damages expert and Dr. Mitchell as Plaintiffs' technical expert), nor is it

proper for Ms. Lawton to parrot the opinions of other experts on technical issues. *Rheault v. Halma Holdings Inc.*, 2025 WL 1866842, at *13 (D. Del. June 30, 2025) (expert "may not offer testimony that is nothing more than a parroting of opinions of others, which he is not qualified on his own to give"). Permitting the damages expert to echo inflammatory opinions on copying and willfulness only invites the jury to punish Moderna. *SUNOCO Partners Mktg. & Terminals L.P. v. Powder Springs Logistics, LLC*, 2020 WL 7330715, at *3 (D. Del. Jan. 13, 2020) ("compensatory damages in patent cases is 'not to punish the infringer'"). Ms. Lawton's intent-based "opinions" are improper and prejudicial and should be excluded.

D. Ms. Lawton's Remaining Opinions Are Not Proper Expert Testimony

Without providing the jury a reliable methodology for calculating damages, the only purpose of Ms. Lawton's testimony would be to skew the damages horizon and encourage the jury to award a big number without regard to the footprint of the invention. *Uniloc*, 632 F.3d at 1320; *Microchip Tech. Inc. v. Aptiv Servs. US LLC*, No. 17-1194-JDW, D.I. 351 at 3 (D. Del. Apr. 5, 2022) (excluding references to revenues and profits not tied to expert's reasonable royalty calculation). Ms. Lawton describes how Moderna made worldwide net sales of $38.3 billion, that Moderna was "charging governments as much as US$41 billion above the estimated cost of production," and that Moderna estimated in May 2020 that its total health economic value potential would be $462 billion through 2021. Ex-A ¶¶9, 55, 57, 314. Plaintiffs should not be permitted to use Ms. Lawton as a mouthpiece to introduce prejudicial figures and irrelevant opinions.

VII. DR. SCHUSTER'S UNRELIABLE TESTING SHOULD BE EXCLUDED

The target ratios of lipid components in Moderna's commercial formulations fall outside the claims of the Ratio Patents. In an effort to prove that Moderna's vaccine contains ***some*** LNPs that fall within the claims of the Ratio Patents, Plaintiffs rely on Dr. Georg Schuster, who oversaw testing of the accused product, to purportedly split the samples up into fractions and measure the

amount of each of the four claimed lipids in each fraction. Dr. Schuster used a combination of two techniques: fractionation by ultracentrifugation ("UC") and measurement of lipid content by chromatography. Samples were placed into tubes and fractionated (*i.e.*, separated) by spinning the tubes millions of times by UC, which purportedly resulted in 10 fractions within each tube. Ex-G §§V.A-V.B; Ex-U §III.A.1. A sample of each fraction was then removed from the tube by pipette, and the amount of the four lipid components in each fraction was measured using chromatography. *Id.* ¶44; Ex-H 114:19-22, 118:3-120:6; Ex-U §III.A.2. Dr. Schuster then used the lipid amounts to calculate the mol% of each lipid. Ex-H 136:7-23; Ex-G ¶95. Dr. Schuster admitted that prior to this lawsuit, he had never used UC for the measurement of lipid content of LNPs and only used this technique at counsel's request. Ex-H 36:15-19, 55:2-12, 58:1-4. Although his expert report described his fractionation method as using "standard [UC] settings," the documents Plaintiffs were compelled to produce revealed that there was nothing "standard" about his tests. Ex-G ¶43, n28; Ex-I ¶¶54-65, 69, 71, 73-74; Ex-J ¶¶415-422; Ex-K ¶¶16, 23; Ex-H 253:21-255:8.

Dr. Schuster's infringement testing opinions should be excluded for two reasons. ***First***, the UC technique is textbook unreliable because it led to ***different*** results for the same fraction of the same sample when using the same test parameters. Indeed, when Dr. Schuster tested the ***same fraction*** of the ***same sample***, using the same UC test parameters (*e.g.*, speed, temperature, duration), PEG mol% varied by as much as 10%. Ex-Q at 781 (*compare* F06_R4_1%Sucrose_01 (2.176 mol%) *with* F06_R4_1%Sucrose_02 (2.393 mol%)); Ex-L 28:13-29:15. Similarly, a particular fraction of the same sample fell within the claimed range of PEG (*e.g.*, '435 Patent claim 7 reciting up to 2.499 mol% PEG lipid) for one run, but the same fraction of the same sample did not fall within the claimed range in a second run. *Id.* (*compare* F08_R4_PBS_01 (2.429 mol%) *with* F08_R4_PBS_02 (2.616 mol%), F07_R4_1%Sucrose_01 (2.483 mol%) *with*

F07_R4_1%Sucrose_02 (2.691 mol%)); Ex-L 32:15-18 ("_01" or "_02" at end of label indicates material came from same fraction of the same sample but differed in injection volume subjected to chromatography). It is plainly unreliable for a test to generate different results for the ***same*** sample, particularly where the difference is dispositive of infringing versus not infringing. *King Drug Co. of Florence Inc. v. Cephalon, Inc.*, 2015 WL 6750899, at *11, 13 (E.D. Pa. Nov. 5, 2015) (excluding testing opinions "as unreliable" where the "same sample of the same product was tested several times using the same methodology," and the results "vary considerably, ranging from infringing to noninfringing").

Plaintiffs attempt to justify Dr. Schuster's use of fractionation testing because Moderna scientists used it as an investigative technique in certain scenarios (*e.g.*, manufacturing failure). But as those scientists made clear, such a technique was used ***qualitatively—not quantitatively***—it cannot reliably measure lipid content because it was not possible to determine whether the method itself was changing the particles. Ex-J §X.D.2.a; Ex-O 26:17-29:5, 35:17-40:4; Ex-P 282:5-286:8; *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1121-23 (S.D. Fla. 2022) (excluding testimony where expert failed to demonstrate test method did not cause change in tested substance); Ex-J ¶¶413, 415-17, 421, 427; Ex-I §VII.B. Dr. Schuster did not attempt to understand, let alone control, the effect his methods had on lipid mol% amounts. *Daubert*, 509 U.S. at 594 (reliability depends on "known or potential rate of error, and the existence and maintenance of standards controlling the technique's operation"); *Zantac*, 644 F. Supp. 3d at 1121 (reliability diminished where expert "proffered no rates of error" for test method).

Second, even assuming the UC method was itself appropriate, Dr. Schuster's methodology was fatally flawed. Although Dr. Schuster characterized his test methods as "standard," the secret rounds of pre-testing by Dr. Schuster that Plaintiffs were compelled to produce revealed that Dr.

Schuster's application of the UC method is the type of "[r]esult-driven analysis" and "cherry-picking" which "[c]ourts have consistently excluded." *In re Lipitor*, 892 F.3d 624, 634 (4th Cir. 2018). Dr. Schuster secretly ***customized*** the parameters of his testing to obtain the results that most favored Plaintiffs. Specifically, Dr. Schuster tested Moderna's samples across eight combinations of varied parameters: temperature, rotor speed, duration, sample volume, sample concentration, and use of sucrose. Ex-K ¶¶18-26. Altering these parameters ***changed*** the resulting mol% of the lipids of the ***same sample***. *Id.* ¶28 (explaining that the lowest amount of SM-102 cationic lipid across all fractions varied by 4 mol%), ¶29 (different parameters altered the number of fractions meeting the limitations of the Ratio Patents); Ex-L 28:19-24. Dr. Schuster chose the set of parameters that resulted in the ***most*** infringing fractions for the tests of the 67 lots that were described in his expert report. Ex-K ¶¶29-31. Although Dr. Schuster presented his comparisons of the various parameters and their impact on the resulting lipid mol% to Plaintiffs' counsel in a slide deck, Dr. Schuster chose to only disclose in his report the parameters that created the most allegedly infringing fractions—disingenuously labelling them as "standard." Ex-K ¶¶29-31; Ex-L 18:7-16, 22:13-23:13; Ex-G ¶43, n28; Ex-Q at 780-785. This is exactly the sort of "results-driven analysis" that will not help the jury. *In re Lipitor*, 892 F.3d at 633-35 (methodology "too tainted with potential bias" where datapoints were selectively chosen, methodology was altered to achieve more favorable results, and less favorable results were omitted).

Dr. Schuster disclosed ***none*** of this in his report. Ex-L 16:9-17:19, 22:13-23:21. Dr. Schuster's actual testing methodology and parameters were only revealed after Moderna moved to compel these materials. D.I. 450. When confronted with his own presentation showing different parameters resulted in different mol% amounts, Dr. Schuster claimed the differences were not true differences in lipid content but an artifact of "analytical variability" of the instruments measuring

lipid content. Ex L 34:8-38:17. But that is based only on his say-so; he admittedly performed ***no*** analysis to determine the cause of the variation, the amount of analytical variability, or whether it was scientifically acceptable. *Id* (discussing variability in results between different parameters shown in Ex-Q at 778). Dr. Schuster also "[didn't] even know if each of th[e] value[s] is [one] hundred percent correct." *Id*. Faced with results showing different parameters changed the resulting mol% of the same sample, he did nothing to determine if and to what extent the parameters of the UC process were altering the lipid mol% of the particles. Ex-K ¶¶23-31; Ex L 34:8-38:17. These methodological flaws mandate exclusion of Dr. Schuster's opinions.

VIII. DR. MITCHELL'S STATE OF MIND AND NON-EXPERT OPINIONS SHOULD BE EXCLUDED

Plaintiffs' main technical expert, Dr. Mitchell, cleared the protective order 14 days before his report was due, and yet claims to have read 20,000+ pages of Moderna documents, 4,300+ pages of transcripts, and hundreds of pages of others' expert reports (including Dr. Schuster's 300+ page report in one day) to prepare his 615-page opening report with a 154 appendices—all in 92 hours.[2] Ex-T 20:2–21:24, 170:25–171:15, 230:15–21; 236–246. That is highly suspect. To the extent it was humanly possible, it is because Dr. Mitchell's report is largely devoid of expert opinions and instead riddled with improper state-of-mind commentary and thinly disguised attorney argument. But Rules 702 and 703 do not "permit parties to cloak attorney argument in the guise of expert testimony." *Wirtgen*, 2024 WL 166833, at *2. Nor do they allow experts "merely to repeat or summarize what the jury independently has the ability to understand." *Crowley v. Chait*, 322 F. Supp. 2d 530, 553 (D.N.J. Mar. 16, 2004). The vast majority of Dr. Mitchell's opinions violate one or both of these principles and should be excluded.

[2] As part of summary judgment briefing, Moderna moved to exclude Dr. Mitchell as a mouthpiece for Plaintiffs' attorney argument. D.I. 596, 623. The dubious authorship of Dr. Mitchell's opening report further colors the lack of reliability, and ergo inadmissibility, of his opinions under *Daubert*.

To start, Dr. Mitchell's report is full of opinions on Moderna's motives and "subjective state of mind," topics on which he "has no knowledge." *Wirtgen*, 2024 WL 166833, at *2. He repeatedly opines, for example, that self-interest drove Moderna's contributions to the LNP field. Ex-E ¶289 ("Moderna ***wanted*** to abandon MC3—likely to avoid intellectual property"); Ex-F ¶161 ("substantial evidence that Moderna transitioned to SM-102 at least in part because of a ***desire*** for a proprietary ionizable lipid and a ***desire*** to not pay royalties"); ¶173 ("Moderna's leadership, including Stephen Hoge" wanted to "***avoid paying to license Plaintiffs' patents***"). These statements impermissibly infer Moderna's intent, warranting exclusion. *Victaulic Co. v. Engineered Sols., LLC*, 2022 WL 17250376, at *8 (D. Del. Nov. 28, 2022) (excluding testimony for improperly opining on state of mind and unfairly prejudicial). They also do "no more than counsel for plaintiffs will do in argument, *i.e.*, propound a particular interpretation of defendant's conduct." *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 2019 WL 5685269, at *9 (D. Mass. Nov. 1, 2019) (excluding expert testimony resting on "[i]nferences about the intent or motive of parties"); *see also Modica v. Maple Meadows Homeowners Ass'n*, 2014 WL 1663150, at *1 n.3 (E.D. Pa. Apr. 2, 2014) (expert testimony may not be used "to repeat or summarize what the jury independently has the ability to understand").

Even putting aside his improper state of mind opinions, large swaths of Dr. Mitchell's report are "merely a matter of his own assessment of the facts," as opposed to an opinion "based on any scientific methodology that would assist the jury in resolving these disputes of fact." *Schneider v. BMW of N. Am., LLC*, 2022 WL 1718996, at *4 (D. Mass. Feb. 22, 2022) (excluding evidence that would "put an expert gloss on a conclusion that the jurors should draw themselves"). For instance, with respect to indirect infringement, Dr. Mitchell relies on Moderna's marketing materials to assert that Moderna has "intentionally and actively engaged in marketing campaigns

. . . to encourage individuals to use and administer Moderna's COVID-19 vaccine." Ex-E ¶767; *see also id.* ¶¶759-81. But Dr. Mitchell's technical credentials do not give him any greater ability than the jury in interpreting marketing materials or Moderna's purported intent, and Plaintiffs cannot back-door attorney argument "in the guise of expert testimony." *Wirtgen*, 2024 WL 166833, at *2 (excluding portions of opinion devoid of any "expert analysis").

The same is true for Dr. Mitchell's willfulness opinions, which are merely "lawyer argument" about Moderna's state of mind based on "objective facts" that should be presented directly to the jury. *Wirtgen*, 2024 WL 166833, at *2; Ex-E ¶¶819-838 ("Moderna's documents and testimony make clear that it was ***aware***" of the Patents-in-Suit); Ex-F ¶832 ("Moderna ***did attempt to conceal*** its infringement"); ¶769 ("Moderna was ***willfully blind*** to the fact, including by taking deliberate steps to avoid the 'uncomfortable questions' about patent infringement); Ex-E ¶¶ 759-781, ¶770 ("Moderna was ***aware*** that the Accused Product infringed"); ¶¶777-78 ("Moderna ***knew*** that these steps taken at its direction would infringe"). None of that speculative testimony falls within Dr. Mitchell's bioengineering expertise—or any expert's expertise. These statements are not "based on any scientific methodology that would assist the jury in resolving these disputes of fact," and instead are "merely a matter of his own assessment of the facts." *Schneider v. BMW of N. Am., LLC*, 2022 WL 1718996, at *4 (D. Mass. Feb. 22, 2022) (excluding evidence that would "put an expert gloss on a conclusion that the jurors should draw themselves"); *see also Oxford Gene Tech. Ltd. v. Mergen Ltd.*, 345 F. Supp. 2d 431, 443 n.9 (D. Del. 2004) (excluding testimony referring to defendants' "concerns" or "recogni[tion]" of infringement); *In re Rosuvastatin Calcium Patent Litig.*, 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009), *r&r adopted*, 2010 WL 661599 (D. Del. Feb. 19, 2010) (similar).

IX. MR. PITTS' AND MR. BRILL'S §1498 OPINIONS SHOULD BE EXCLUDED

Expert evidence is not necessary to resolve the applicability of Moderna's § 1498

affirmative defense. Rather, it is a purely legal issue of statutory interpretation for the Court, as noted in Moderna's pending Motion for Summary Judgment. D.I. 508, 509, 510, 511, 596, 597, 598, 599. Nevertheless, Plaintiffs' § 1498 experts offer commentary that the benefits of Moderna's vaccine inured only to individuals or the American public, not the Government, Ex-M ¶¶24, 29-38; Ex-N ¶¶18, 40, 65, 68, and make public policy arguments as to future consequences should § 1498 be applicable in this case, Ex-M ¶¶59-62; Ex-N ¶¶28-29. They do not describe any principles, methods, or objective criteria for offering these opinions, which warrant their exclusion.

First, expert evidence is not necessary to resolve whether Moderna's production of 500 million doses of its COVID-19 vaccine for the Government pursuant to a procurement contract containing a § 1498 FAR clause falls within the statutory standard set forth in 28 U.S.C. § 1498 ("Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States . . . ."). "Statutory interpretation is a question of law reserved for the Court." *Shell Petroleum, Inc. v. United States*, 996 F. Supp. 361, 366 (D. Del. 1997), *aff'd*, 182 F.3d 212 (3d Cir. 1999); *Sevenson Env't Servs., Inc. v. Shaw Env't, Inc.*, 477 F.3d 1361, 1364 (Fed. Cir. 2007).

Second, Mr. Pitts' and Mr. Brill's opinions are not expert evidence but policy arguments about why § 1498 should not apply in this case. Mr. Pitts claims that application of § 1498 would "dramatically expand the potential liability of the federal government for patent infringement by private parties," which "would have enormous impacts if taken to its logical conclusion." Ex-M ¶¶59-60. Mr. Pitts then forewarns of doomsday "broader consequences" such as a "future [of] prescription drug acquisitions by the federal government." *Id.* ¶¶60-63 (discussing hypothetical purchases of Hepatitis C drugs). Similarly, Mr. Brill argues cost savings realized by the Government ignores long-run impacts because "living longer means people may develop other

ailments that increase lifetime health care costs." Ex-N ¶¶39-51. "[P]olicy opinions" may be the appropriate subject of congressional testimony about proposed amendments to § 1498, but they are not the appropriate subject of "expert" testimony. *SEC v. Ambassador Advisors, LLC*, 576 F. Supp. 3d 250, 260 (E.D. Pa. 2021); *see also Apple Inc. v. Corellium, LLC*, 2020 WL 5417197, at *5 (S.D. Fla. July 30, 2020), *r&r adopted*, 2020 WL 7385752 (S.D. Fla. Dec. 16, 2020) (similar).

Third, the remainder of these experts' reports describes their views on whether doses of Moderna's vaccine that were dispensed to members of the public during Operation Warp Speed provided a "benefit" to the Government. Ex-N ¶¶28-38; Ex-M ¶¶ 29-38. Even if this Court were to agree with Plaintiffs that § 1498 requires a separate showing of a benefit to the Government (beyond the statutory requirement that the product was "manufactured . . . for the government"), and that there is a factual dispute on that question, Mr. Brill's and Mr. Pitts' testimony would *still* be inadmissible. Neither "expert" purports to offer, much less apply, any objective principles or methodology to opining on this question. Instead, their expert reports "read[] more like an amicus brief than an expert report," relying on legal and policy materials such as articles from think tanks. *Suprock v. Quantum Energy, Inc.*, 676 F. Supp. 3d 891, 895 (D. Nev. 2023) (excluding report that was "nothing more than a legal opinion dressed up as an expert one"). Accordingly, even as to the "benefit to the government" question, these experts offer nothing more than their "untestable" views of what should, and should not, constitute a benefit to the Government, which improperly "render[s] the Court powerless to perform its gatekeeping function." *Lewis v. Cain*, 2017 WL 4782653, at *2 (M.D. La. Oct. 23, 2017). Messrs. Pitts' and Brill's opinions should be excluded.

X. CONCLUSION

For the reasons set forth above, the opinions of Plaintiffs' experts should be excluded.

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November 7, 2025

CERTIFICATE OF SERVICE

I hereby certify that on December 16, 2025, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on December 16, 2025, upon the following in the manner indicated:

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